

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

COSMO TECHNOLOGIES LIMITED and
SANTARUS, INC.,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

C.A. No. 1:15-cv-00116-LPS

**DEFENDANT PAR PHARMACEUTICAL, INC.'S
ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendant Par Pharmaceutical, Inc. (“Par” or “Defendant”), by and through its attorneys, for its Answer to the Complaint of Plaintiffs Cosmo Technologies Limited (“Cosmo”) and Santarus, Inc. (“Santarus”) (collectively, “Plaintiffs”), hereby declares as follows:

PARTIES

1. Par is without knowledge and information sufficient to form a belief as to the country of incorporation and principal place of business of Cosmo. Par thus denies the allegations of Paragraph 1.

2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Santarus. Par thus denies the allegations of Paragraph 2.

3. Par admits it is a corporation organized and existing under the laws of the State of Delaware. Par admits it has a principal place of business at One Ram Ridge Road, Spring Valley, NY 10977. Par avers that it is a pharmaceutical company engaged in developing,

manufacturing, and distributing, *inter alia*, generic pharmaceutical products through the United States, including in this judicial district. Par denies the remaining allegations of Paragraph 3.

NATURE OF THE ACTION

4. Paragraph 4 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the Complaint purports to be a civil action for patent infringement of United States Patent No. 7,410,651 (the “651 patent”); U.S. Patent No. 7,431,943 (the “943 patent”); U.S. Patent No. 8,293,273 (the “273 patent”); U.S. Patent No. 8,784,888 (the “888 patent”); U.S. Patent No. 8,895,064 (the “064 patent”); and U.S. Patent No. RE 43,799 (the “799 patent”) (collectively, the “patents-in-suit”). Par further admits that the Complaint purports to be an action that arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

JURISDICTION AND VENUE

5. Paragraph 5 states a legal conclusion to which no response is required. To the extent a response is required, Par admits this Court has jurisdiction over the subject matter of this action only. Par denies the remaining allegations of Paragraph 5.

6. Paragraph 6 states a legal conclusion to which no response is required. To the extent a response is required, Par admits personal jurisdiction in this judicial district for the limited purposes of this action only. Par denies the remaining allegations of paragraph 6.

7. Par denies the allegations of Paragraph 7.

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base venue on 28 U.S.C. §§ 1391 and 1400(b). Par does not contest venue in this judicial district for the limited purpose of this action only. Par denies the remaining allegations of Paragraph 8.

THE PATENTS-IN-SUIT

9. Par admits that the '651 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as August 12, 2008. Par further admits that what appears to be a copy of the '651 patent is attached to the Complaint as Exhibit A. Par denies that the United States Patent and Trademark Office duly and legally issued the '651 patent, and the remaining allegations of Paragraph 9.

10. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 10, and thus denies the same.

11. Par denies that the '943 patent is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition." Par admits that the '943 patent, on its face, states its date of issue as October 7, 2008. Par further admits that what appears to be a copy of the '943 patent is attached to the Complaint as Exhibit B. Par denies that the United States Patent and Trademark Office duly and legally issued the '943 patent, and the remaining allegations of Paragraph 11.

12. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 12, and thus denies the same.

13. Par admits that the '273 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as October 23, 2012. Par further admits that what appears to be a copy of the '273 patent is attached to the Complaint as Exhibit C. Par denies that the United States Patent and Trademark Office duly and legally issued the '273 patent, and the remaining allegations of Paragraph 13.

14. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 14, and thus denies the same.

15. Par admits that the '888 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as July 22, 2014. Par

further admits that what appears to be a copy of the '888 patent is attached to the Complaint as Exhibit D. Par denies that the United States Patent and Trademark Office duly and legally issued the '888 patent, and the remaining allegations of Paragraph 15.

16. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 16, and thus denies the same.

17. Par admits that the '064 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as November 25, 2014. Par further admits that what appears to be a copy of the '064 patent is attached to the Complaint as Exhibit E. Par denies that the United States Patent and Trademark Office duly and legally issued the '064 patent, and the remaining allegations of Paragraph 17.

18. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 18, and thus denies the same.

19. Par admits that the '799 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as November 13, 2012. Par further admits that what appears to be a copy of the '799 patent is attached to the Complaint as Exhibit F. Par denies that the United States Patent and Trademark Office duly and legally issued the '799 patent, and the remaining allegations of Paragraph 19.

20. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 20, and thus denies the same.

ACTS GIVING RISE TO THIS ACTION¹

21. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 21, therefore Par denies that Santarus holds New Drug Application

¹ Headings are reprinted here with the same language as used in Plaintiffs' Complaint simply for ease of reference, and do not constitute an admission by Par.

(“NDA”) No. 203634 for oral tablets containing 9 mg of the active ingredient budesonide associated with its trade name Uceris. Par also denies that Uceris is indicated for the treatment of mildly to moderately active ulcerative colitis. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 21, and thus denies the same.

22. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 22, and thus denies the same.

23. Par admits that it submitted Abbreviated New Drug Application (“ANDA”) No. 206131 to the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, or sale of tablets containing 9 mg of budesonide (“Par’s ANDA Product”) prior to the expiration of the ’651 patent, the ’943 patent, the ’273 patent, the ’888 patent, the ’064 patent, and the ’799 patent.

24. Par admits that ANDA No. 206131 contained a certification stating that the claims of the ’651 patent, the ’943 patent, the ’273 patent, the ’888 patent, the ’064 patent, and the ’799 patent are invalid, unenforceable, and/or will not be infringed. Par denies the remaining allegations of Paragraph 24.

25. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 25, therefore Par denies the allegations of Paragraph 25.

26. Paragraph 26 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 26.

27. Par admits that its Notice Letter sent to Plaintiffs included an Offer of Confidential Access (“OCA”) to certain Par confidential information regarding Par’s ANDA Product. Par admits that it negotiated with Plaintiffs the terms for Par’s OCA. Par admits that the parties were not able to reach agreement with respect to the revisions to the terms of Par’s OCA that Plaintiffs proposed. Par denies the remaining allegations of Paragraph 27.

28. Par admits that it has not yet provided Plaintiffs with a copy of any portions of its ANDA or any information regarding Par's ANDA Product, beyond information that was set forth in Par's Notice Letter. Par denies the remaining allegations of Paragraph 28.

29. Paragraph 29 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 29.

FIRST COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 7,410,651

30. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 29 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 29.

31. Par denies the allegations of Paragraph 31.

32. Par denies the allegations of Paragraph 32.

33. Par denies the allegations of Paragraph 33.

34. Par denies the allegations of Paragraph 34.

35. Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 35.

SECOND COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 7,431,943

36. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 35 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 35.

37. Par denies the allegations of Paragraph 37.

38. Par denies the allegations of Paragraph 38.

39. Par denies the allegations of Paragraph 39.

40. Par denies the allegations of Paragraph 40.

41. Paragraph 41 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 41.

THIRD COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 8,293,273

42. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 41 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 41.

43. Par denies the allegations of Paragraph 43.

44. Par denies the allegations of Paragraph 44.

45. Par denies the allegations of Paragraph 45.

46. Par denies the allegations of Paragraph 46.

47. Paragraph 47 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 47.

FOURTH COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 8,784,888

48. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 47 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 47.

49. Par denies the allegations of Paragraph 49.

50. Par denies the allegations of Paragraph 50.

51. Par denies the allegations of Paragraph 51.

52. Par denies the allegations of Paragraph 52.

53. Paragraph 53 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 53.

FIFTH COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 8,895,064

54. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 53 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 53.

55. Par denies the allegations of Paragraph 55.

56. Par denies the allegations of Paragraph 56.

57. Par denies the allegations of Paragraph 57.

58. Par denies the allegations of Paragraph 58.

59. Paragraph 59 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 59.

SIXTH COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. RE 43,799

60. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 59 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 59.

61. Par denies the allegations of Paragraph 61.

62. Par denies the allegations of Paragraph 62.

63. Par denies the allegations of Paragraph 63.

64. Par denies the allegations of Paragraph 64.

65. Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 65.

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to the relief they seek in Paragraphs A–J or any relief at all for the allegations made in the Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Plaintiffs' allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Par reserves the right to allege additional defenses in the event that discovery or other analysis indicates that additional affirmative or other defenses are appropriate.

FIRST SEPARATE DEFENSE

66. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

67. The claims of the '651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent, and the '799 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

THIRD SEPARATE DEFENSE

68. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent, and the '799 patent.

69. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent, and the '799 patent under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE

70. Par's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par") asserts the following Counterclaims against Cosmo Technologies Limited and Santarus, Inc. (collectively "Plaintiffs"): (1) United States Patent No. 7,410,651 (the "'651 patent"); U.S. Patent No. 7,431,943 (the "'943 patent"); U.S. Patent No. 8,293,273 (the "'273 patent"); U.S. Patent No. 8,784,888 (the "'888 patent"); U.S. Patent No. 8,895,064 (the "'064 patent"); and U.S. Patent No. RE 43,799 (the "'799 patent") (collectively, "the patents-in-suit") are not infringed by the product described in ANDA No. 206131 and/or (2) are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

THE PARTIES

1. Par is a corporation organized and existing under the laws of Delaware with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

2. Based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Cosmo Technologies Limited ("Cosmo") is an Irish corporation, having its principal place of business at Connolly Building, 42-43 Amiens Street, Dublin, Ireland.

3. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Santarus, Inc. ("Santarus") is a Delaware corporation, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615.

NATURE OF THE ACTION

4. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declarations that the patents-in-suit are not infringed by the product described in Par's ANDA No. 206131 and/or are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, as well as 21 U.S.C. § 355(c)(3)(D).

6. This Court has personal jurisdiction over Plaintiffs based on, *inter alia*, Plaintiffs' filing of this lawsuit in this jurisdiction. This Court further has personal jurisdiction over Santarus because Santarus is a corporation organized and existing under the laws of the State of Delaware and by virtue of, *inter alia*, having availed itself of the rights and benefits of Delaware law and having engaged in systematic and continuous contacts with the state of Delaware.

7. Venue is proper in this judicial district based on 28 U.S.C. §§ 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

8. The '651 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as August 12, 2008.

9. The '943 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Compositions," and states its date of issue as October 7, 2008.

10. The '273 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as October 23, 2012.

11. The '888 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as July 22, 2014.

12. The '064 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as November 25, 2014.

13. The '799 patent, on its face, is titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," and states its date of issue as November 13, 2012.

14. On information and belief, and based on Plaintiffs' allegations, Cosmo is the owner of the '651, '943, '273, '888, '064, and '799 patents.

15. On information and belief, and based on Plaintiffs' allegations, Santarus holds exclusive licenses to the '651, '943, '273, '888, '064, and '799 patents.

16. On information and belief, the FDA approved NDA No. 203634 on January 14, 2013.

17. The '651, '943, '273, '888, '064, and '799 patents are listed in the FDA's Orange Book for NDA No. 203634.

18. Par submitted ANDA No. 206131 to the FDA, requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of tablets containing 9 mg of budesonide before the expiration date of the '651, '943, '273, '888, '064, and '799 patents. Par made a certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the '651, '943, '273, '888, '064, and '799 patents would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the products that are the subject of ANDA No. 206131 ("Par's ANDA Product").

19. On December 19, 2014, Par sent a letter to Plaintiffs stating that ANDA No. 206131 contained a Paragraph IV Certification regarding the patents-in-suit.

20. On February 2, 2015, Plaintiffs filed their complaint alleging infringement by Par of the '651, '943, '273, '888, '064, and '799 patents.

FIRST COUNT
(Declaration of Invalidity of the '651 Patent)

21. Par incorporates by reference Paragraphs 1 through 20 as if fully set forth herein.

22. The claims of the '651 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

23. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '651 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

24. Par is entitled to a judicial declaration that the '651 patent is invalid.

SECOND COUNT
(Declaration of Noninfringement of the '651 Patent)

25. Par incorporates by reference Paragraphs 1 through 24 as if fully set forth herein.

26. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '651 patent.

27. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '651 patent under the doctrine of equivalents.

28. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '651 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

29. Par is entitled to a judicial declaration that the '651 patent is not infringed.

THIRD COUNT
(Declaration of Invalidity of the '943 Patent)

30. Par incorporates by reference Paragraphs 1 through 29 as if fully set forth herein.

31. The claims of the '943 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

32. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '943 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

33. Par is entitled to a judicial declaration that the '943 patent is invalid.

FOURTH COUNT
(Declaration of Noninfringement of the '943 Patent)

34. Par incorporates by reference Paragraphs 1 through 33 as if fully set forth herein.

35. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '943 patent.

36. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '943 patent under the doctrine of equivalents.

37. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '943 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

38. Par is entitled to a judicial declaration that the '943 patent is not infringed.

FIFTH COUNT
(Declaration of Invalidity of the '273 Patent)

39. Par incorporates by reference Paragraphs 1 through 38 as if fully set forth herein.

40. The claims of the '273 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

41. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '273 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

42. Par is entitled to a judicial declaration that the '273 patent is invalid.

SIXTH COUNT
(Declaration of Noninfringement of the '273 Patent)

43. Par incorporates by reference Paragraphs 1 through 42 as if fully set forth herein.

44. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '273 patent.

45. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '273 patent under the doctrine of equivalents.

46. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '273 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

47. Par is entitled to a judicial declaration that the '273 patent is not infringed.

SEVENTH COUNT
(Declaration of Invalidity of the '888 Patent)

48. Par incorporates by reference Paragraphs 1 through 47 as if fully set forth herein.

49. The claims of the '888 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

50. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '888 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

51. Par is entitled to a judicial declaration that the '888 patent is invalid.

EIGHTH COUNT
(Declaration of Noninfringement of the '888 Patent)

52. Par incorporates by reference Paragraphs 1 through 51 as if fully set forth herein.

53. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '888 patent.

54. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '888 patent under the doctrine of equivalents.

55. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '888 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

56. Par is entitled to a judicial declaration that the '888 patent is not infringed.

NINTH COUNT
(Declaration of Invalidity of the '064 Patent)

57. Par incorporates by reference Paragraphs 1 through 56 as if fully set forth herein.

58. The claims of the '064 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

59. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '064 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

60. Par is entitled to a judicial declaration that the '064 patent is invalid.

TENTH COUNT
(Declaration of Noninfringement of the '064 Patent)

61. Par incorporates by reference Paragraphs 1 through 60 as if fully set forth herein.

62. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '064 patent.

63. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '064 patent under the doctrine of equivalents.

64. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '064 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

65. Par is entitled to a judicial declaration that the '064 patent is not infringed.

ELEVENTH COUNT
(Declaration of Invalidity of the '799 Patent)

66. Par incorporates by reference Paragraphs 1 through 65 as if fully set forth herein.

67. The claims of the '799 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

68. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '799 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

69. Par is entitled to a judicial declaration that the '799 patent is invalid.

TWELFTH COUNT
(Declaration of Noninfringement of the '799 Patent)

70. Par incorporates by reference Paragraphs 1 through 69 as if fully set forth herein.

71. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '799 patent.

72. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '799 patent under the doctrine of equivalents.

73. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '799 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

74. Par is entitled to a judicial declaration that the '799 patent is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par requests the following relief:

- a) Dismissing Plaintiffs' Complaint with prejudice and denying each request for relief made by Plaintiffs;
- b) Declaring all claims of the '651 patent invalid;
- c) Declaring all claims of the '651 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- d) Declaring all claims of the '943 patent invalid;
- e) Declaring all claims of the '943 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- f) Declaring all claims of the '273 patent invalid;
- g) Declaring all claims of the '273 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- h) Declaring all claims of the '888 patent invalid;
- i) Declaring all claims of the '888 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- j) Declaring all claims of the '064 patent invalid;
- k) Declaring all claims of the '064 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

- l) Declaring all claims of the '799 patent invalid;
- m) Declaring all claims of the '799 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- n) Declaring that Par has a lawful right to obtain FDA approval for the product as described in ANDA No. 206131 and that Par has a lawful right to manufacture, import, use, sell, and/or offer to sell the product as described in ANDA No. 206131;
- o) Shortening the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) to expire immediately;
- p) Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding Par its attorneys' fees, costs, and expenses in this action; and
- q) Awarding Par such other and further relief as the Court deems just and proper.

Dated: February 26, 2015

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Of Counsel:

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on February 26, 2015, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served by e-mail upon the following counsel of record:

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